DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-30

January 31, 2001

FACILITY ID # 213470

Keith Hall, Director
Delray Medical Center
10075 Job Road Suite 100
Boynton Beach, Florida 33437

Dear Mr. Hall:

We are writing to you because on January 23, 2001, a representative of the State of Florida, acting in behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 and 2 findings at your facility:

Level 1: Mammograms were processed when the X-OMAT M35 Kodak processor was out of limits for sixteen days.

Level 2: Corrective actions for processor QC failures were not documented at least once for the Kodak processor.

X-OMAT M35 processor QC records were missing for three consecutive days out of fifteen during operation in October 2000.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure

to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).*

Please submit your response to Timothy J. Couzins, Compliance Officer, U.S. Food & Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact D. Janneth Caycedo, Consumer Safety Officer, Food and Drug Administration, Boca Raton Resident Post, at 561-338-5236 ext 23.

Sincerely yours,

Emma R. Singleton
Director, Florida District